

EARLY VERSUS LATE REPAIR OF INCISIONAL HERNIA FOLLOWING LAPAROSTOMY FOR ENTER CUTANEOUS FISTULAS USING COMPONENT SEPARATION TECHNIQUE AND ONLAY PLACEMENT OF POLYPROPYLENE MESH

Adil Bangash¹, Ayaz Gul ¹, Ahmad Faraz¹, Shumaila Naseer¹, Sara Jamil Khan², Aziz Ur Rehman³

¹Surgical Division, Department of Surgery, Lady Reading Hospital, Peshawar

²Department of Obstetrics and Gynaecology, Frontier Medical College, Abbottabad

³Department of Surgery, North West School of Medicine, Peshawar

ABSTRACT

Objectives: To compare the outcome of early versus late repair of incisional hernia that developed following laparostomy for enterocutaneous fistula.

Materials and Methods: This Randomized controlled trial study was conducted at Surgical Unit, Lady Reading Hospital, Peshawar from 22nd May, 2014 till 21st May, 2017. Following ethical approval, 69 patients were enrolled in the study, amongst which three were lost to follow-up. So, 33 patients in both groups were later on included. In group A, patients were asked to present at an early 3-month delay following confirmation of successful enterocutaneous fistula management after discharge, and Group B patients were asked to come one year later. Both groups were subjected to the same procedure of component separation technique with reinforcement with polypropylene mesh. Data was recorded on a Proforma and post-operative complications were mentioned for a period of 12 months that included seroma/hematoma formation, superficial wound infection, mesh infection, enterocutaneous fistulas, recurrence and mortality.

Results: Following allocation to two groups, the group planned for surgery by the component separation technique (CST) in the early group had a slightly smaller hernia (21.3cm) but this was not significant a difference in comparison ($p=0.68$). The study was focused at a follow-up for duration for one year during which 19 patients (28.7%) in total had clinical or radiological evidence of recurrence of the incisional Hernia out of which ten patients (30.3%) were from group A. Recurrence in group B occurred in 9 patients (27.2%) ($p=0.88$) This included three patients (4.5%) from both groups with infected meshes that needed removal.

Conclusion: Component Separation technique is a feasible staged approach to management of a ventral wall defect (incisional hernia) with reinforcement of the wall with polypropylene mesh in early phase of recovery after enterocutaneous fistulas.

Key words: Incisional hernia, Early Repair, Enterocutaneous fistula, Laparostomy

INTRODUCTION

Incisional hernias are a common finding in pa-

Correspondence:

Ayaz Gul

Assistant Professor, Surgical Department,

Lady Reading Hospital, Peshawar

Cell: +923339179481

Email: drayazgul333@gmail.com

tients operated with a midline Laparostomy wound. Despite the development and technology to deal with intra-abdominal surgery the frequency of incisional hernias after a laparotomy varies from 2-20%¹. Added to the risk of wound dehiscence following laparotomy is the grave chances of not anticipating an enterocutaneous fistula during management². Late presentations of tuberculous peritonitis and perfo-

rated viscus are a common finding in these patients. Inadvertent attempts at closure of an edematous wall increase the risk of enterocutaneous fistulas, which in itself results in increased mortality.

Following prolonged treatment and management of spontaneously closed abdomen following management of Enterocutaneous fistulas remain a challenge. Earlier concepts of timing of surgery to deal with the ventral defect had raised fears of further injury to small bowel and a re-possibility of enterocutaneous fistula⁴. With introduction of the component separation technique and more variety of meshes an earlier repair of these hernias contradicting earlier retrospective studies on the timing of surgery varied from 2-292 days⁴⁻⁸. There is now class I evidence to support that no attempt should be made in patients to repair an incisional hernia before 3 months, yet many surgeons propose that this should not be hastened before one year⁹.

Patients with incisional hernia have decreased quality of life and days off work than the general population that subjects them to grave losses, suggesting that an earlier safe repair is warranted with resumption to daily activities¹⁰. Following Laparotomy and re-epithelialization the overlying layers are strongly adherent to the small bowel, but with the more lateral dissection and mobilization of the anterior rectus sheath and placement of an onlay mesh can result in fewer chances of injury yet a less than compromised repair¹¹⁻¹⁴. The success rates following repair of incisional hernias are very variable with recurrence rates 6-52%¹⁵⁻¹⁸.

With similar rates of recurrence, the results of early repair remain the same according to a study conducted by de Varies et al. where a series of 43 patients with very large hernias were treated by the component separation technique and a recurrence rate at 15 months of 32% was comparable with results of late repairs¹³. With no exposed surface of small bowel, the use of conventional heavy weight polypropylene mesh remains a good option for providing ridged support. The rationale of this study was to compare the timing of the procedure as undue delay causes an inferior quality of life following the development of an Incisional hernia. (rephrase)

MATERIALS AND METHODS

This interventional trial study was conducted at

Surgical C unit, Lady Reading Hospital, Peshawar from 22nd May, 2014 till 21st May, 2017. Following ethical approval, all patients managed with enterocutaneous fistula with laparostomies following laparotomy (midline) for viscus perforation were enrolled and included in the study. In a follow-up study based on data from the Danish Hernia Database the recurrence rate after elective, primary incisional hernia repair was as high as 37%¹². Consideration that an early repair would possess a substantially higher recurrence rate and considering the rarity of the procedure and the complication of enterocutaneous fistulas, a margin of error of 10% with a confidence interval of 90% was selected which calculated for 63 patients to be enrolled. Patients with evidence of malignancy were ruled out of the study. On completion of their treatment for fistulas (enterocutaneous), they were followed for a period designated to the management of their abdominal wall defects.

All patients with enterocutaneous fistula were informed of their inclusion in the study and a written (informed) consent was obtained. By alternately allocating each patient to one of two groups A & B they were followed with particular mention to their nutritional status. Group A patients included those that were asked to present at an early 3-month delay following confirmation of successful enterocutaneous fistula management after discharge from the hospital and Group B patients were asked to come one year later. Both groups were subjected to the same procedure of component separation technique with reinforcement with polypropylene mesh. Pre-operatively, complete blood count, serum albumin, serum electrolytes, renal function tests and Liver function tests were performed. Patients with cough and constipation were delayed till no symptoms of straining were observed. Further investigation was advised by the attending physicians and anesthetists to anticipate any complications beyond surgical complications.

A proforma carrying all this data and data from the previous surgery were recorded and post-operative complications were mentioned for a period of 12 months that included seroma/hematoma formation, superficial wound infection, size of defect, mesh infection, enterocutaneous fistulas, recurrence and mortality. Data collected in the process of the study was incorporated in to the SPSS version 16.0. Demographic data regarding gender, age, duration

of treatment for enterocutaneous fistula, cause for the first surgery and size of the defect in greatest dimensions were compared between groups to rule out a confounding factor, which was also followed with a multi-variate analysis from results of the complications. All qualitative data such as seroma/hematoma formation, infections and mortality were compared using chi square test. Continuous data was compared using student t test. Following comparison, a p value of <0.05 was considered as significant.

RESULT

During the five-year period from May, 2012 till May, 2017 there were 1786 laparotomies performed, that includes both elective and emergent cases. Following these 93 patients had complications and development of enterocutaneous fistula (5.2%) with Laparostomy. During management of the enterocutaneous fistulas 24 patients succumbed to their disease and could not be part of the study.

The remaining 69 patients were enrolled at points during the phase of the study and alternately

placed in two groups. During the process of data collection 2 patients from group A and one patient from group B were lost during follow-up and these were excluded from the study.

This also included 17 cases (0.95%) of gangrenous gut secondary to mesenteric ischemia, with grave consequences and extension of the disease, few if none at all, surviving. In this cases series only one (5.8%) out of 17 cases survived and required prolonged parenteral nutrition but the cause of ischemia could not be elucidated. Of the twenty-four cases that did not respond to treatment for high fistulas majority were mesenteric ischemia (66.6%), where as other cases were firearm injuries with multiple perforations (16.6%), tuberculous abdomen (12.5%) and post total colectomy with ileoanal pouch (4.16%). Varying techniques like repeated bedside washes, Vacpac and application of Bogota's bags were utilized to treat condition with replacement of nutritional losses with total parenteral nutrition via a central subclavian line (catheter). Following recovery from the condition 69 patients were now presenting to the out-patient

Table 1: Demographics, Defect and details of first laparotomy

	Group A n=33	Group B n=33	P value
	31.6(+11.2)	34.4(+13.6)	0.861 t
Gender			
Male	19	22	0.57
Female	14	11	
Hb% (g/dl)(s.d)	10.8(+3.7)	10.2(+4.1)	0.78 t
Serum Albumin (g/l) (s.d)	3.21(+1.6)	3.42(+1.5)	0.71 t
Mean Duration of treatment For fistula (days) (s.d)	25.5(+12.9)	31.6(+16.8)	0.15 m
Length of defect (cm) (s.d)	21.3(+6.7)	23.4(+8.1)	0.68 t
Indication for first surgery			0.88 κ
• Perforated duodenum	01(3.03%)	02(6.06%)	
• Enteric perforation	09(27.2%)	08(24.2%)	
• Tuberculous peritonitis	08(24.2%)	09(27.2%)	
• Necrotizing pancreatitis	02(6.06%)	01(3.03%)	
• Perforated appendicitis	03(9.09%)	04(12.1%)	
• Intestinal obstruction	03(9.09%)	04(12.1%)	
• Road traffic accidents	01(3.03%)	00	
• Gun shot injuries	03(9.09%)	04(12.1%)	
• Spontaneous perforation of colon	01(3.03%)	00	
• others	02(6.06%)	01(3.03%)	
Mean Post-operative hospital stay (days) (s.d)	4.89(+2.8)	5.18(+2.4)	0.33 t

Student t test: t; Chi Square test: χ^2 ; Kruskal wallis test: κ; Mann whitney U test: m

department for the treatment of their hernias. These were large hernias that resulted following dehiscence in a midline incision, with some still having evidence of wound discharge and granulation tissue overlying the underlying fragile small bowel. The mean size of the defects from the skin edges measured by attending surgeon in the outpatient department was 22.35cm. Following allocation to two groups the group planned for surgery by the component separation technique (CST) in the early group had a slightly smaller hernia (21.3cm) but this was not significant a difference in comparison. ($p=0.68$)

With the duration of treatment of fistula averaging 25.5 days and prolonged follow-up, the time since first surgery till repair of incisional hernia in Group A varied from 113 days to 151 days. This duration was much higher in the group B that had repair at nearly one year after management of the enterocutaneous fistula (mean 389 days). The mean age group in the patients from group B (operated after one year) was slightly higher than the patients from group A but this was not significant ($p=0.861$). With a non-significant dominance of female gender in both groups, multi variate analysis failed to reveal a difference between groups for the variability of disease for which the first surgery was performed ($p=0.88$). The nutritional status was assessed by using serum Albumin and Hemoglobin levels and was compared between groups that were also not significant for a difference. The most common presentation for the first laparotomy was enteric perforation (25.7%) and tuberculous peritonitis (25.7%). There were three cases of necrotizing pancreatitis (4.54%) that required repeated necrosectomy for which a prolonged phase of treatment was scheduled. The average age was 26.1 years and all three patients recovered with no documented glucose intolerance or steatorrhea. There were seven cases (10.6%) of perforated appendicitis, intestinal obstruction (small bowel) and Gunshot Injuries in the list of laparotomies which resulted in enterocutaneous fistulas.

Following surgery for the management of incisional hernia, the average stay following CST and placement of polypropylene mesh (heavy weight) was slightly higher in Group B with an average of 5.18 days but this difference was not significant. average stay of patients from the same group.

Following superficial wound infection, observa-

tion of seroma formation was observed as the most common complication in both groups despite placement of suction drains (Redivac) placed bilaterally. Removal of drain was at discretion of the attending physicians with majority patients being discharged after removal of the drain, although some patients were discharged with drains and asked to come for removal of drains at a later date. Seromas were managed in the out-patient department with reassurance to patients regarding the condition. Majority settled with repeated aspiration with two patients (6%) (one from each group) requiring re-placement of drains under local anesthesia.

Three cases (4.5%) from both groups required complete or partial removal of mesh due to non-resolving discharge from wound. The removal of mesh was performed under General anesthesia and patients were called for re-admission following resolution at a later date. These patients were placed in the recurrence category as they required a re-surgery for correction of their incisional hernia.

A significant difference was observed with the CST for treatment of incisional hernia in the group A (15.1%) with a p value of 0.021 and in comparison, only one case from group B presented with gangrenous skin flap. This is a known complication of the procedure but a very ominous difference in Group A was a pitfall of the study, opposing the hypothesis. These patients needed prolonged hospitalization and plastic surgical techniques to fill a defect.

To the surprise of results from the statistics there were two cases (6%) from group A that ended with evidence of gut perforation per-operatively for which gut repair was done and the procedure was abandoned. Both cases were admitted for a prolonged duration and again managed for fistulas, but early recovery was observed with end of the road for these patients in the study. Due to less number of cases the test for significance was inconclusive for risk of inadvertent injury to small bowel in Group A.

The study was focused at a follow-up for duration for one year during which 19 patients (28.7%) in total had clinical or radiological evidence of recurrence of the incisional Hernia. This included three patients (4.5%) from both groups with infected meshes that needed removal. These patients were counseled and were planned for surgery at a later date. The earliest recorded hernias were at 4 months

Table 2: Complications and Hospital Stay

Complication	Group A n=33	Group B n=33	P value
Seroma	06(18.1%)	08(24.2%)	0.18 χ^2
Hematoma	02(6.06%)	03(9.09%)	0.23 χ^2
Superficial wound infection	13(39.3%)	09(27.2%)	0.07 χ^2
Infected mesh	02(6.06%)	01(3.03%)	0.52 χ^2
Gangrenous skin flap	05(15.1%)	01(3.03%)	0.021 χ^2
Subacute intestinal obstruction till 12 months	03(9.09%)	04(12.1%)	0.67 χ^2
Enterocutaneous fistula	02(6.06%)	00	0.06 χ^2
Recurrence at 12 months	10(30.3%)	09(27.2%)	0.88 χ^2
Mortality	00	00	

Student t test: t ; Chi Square test: χ^2 ;

interval after CST but the timing of the procedure and recurrence at varying points was not part of the study.

DISCUSSION

Incisional hernias with its diversity and variable results from surgical management are a great challenge for surgeons around the world. Some centers report less than 4% of incisional hernias following laparotomy for both emergency and elective services rendered but the situation widely varies depending upon the disease presentation²¹. Our study was particularly focused on a growing epidemic of late presenting emergent cases that failed to resolve and ended up with enterocutaneous fistula leaving no option but to treat the fistula prior to any attempt at repair of a ventral defect.

A minimum of three months versus a preferable delay of 12 months has been widely practiced. Our study took into consideration an early repair and early resumption to normal activities in patients who had a prolonged history of hospitalization. Johnson et al.⁹ advocated that a simple pinch test can differentiate that the underlying contents of the peritoneal cavity are separate from the overlying skin as an adequate test. But using Component separation technique (CST), the procedure begins with much lateral dissection focused to medializing the rectus sheath from underlying internal oblique and transversus abdominis muscles with ease, yet covering the defect adequate to the placement of a mesh. This has been recommended by Ramirez et al.²² but the argument to a staged approach versus a single stage procedure to deal with both the fistula and the defect lacks evidence and for that matter with grave ethical issues⁴.

The argument to using the component sepa-

ration technique (CST) as an isolated procedure to management of post-fistula incisional hernia or as a combination with reinforcement with a mesh (prosthetic) is debatable. In one study conducted by Rosen et al.²³ the author advocates the use of intra operative tensiometry to decide the best procedure but the use of CST is based on the fact that reinforcement causes no added tension. With the fear of an infected mesh following such an undertaking is debatable because, in our study only three cases of infected mesh were reported unlike a study conducted by Ewart et al.²⁴ where a much higher number of patients (38%) required removal of mesh following infection performing hernioplasty with a Polytetrafluoro-ethylene (PTFE) mesh in 39 patients. Moreover the comparison showed an unacceptably higher rate of recurrence in the CST group only supporting our nothing of a durable CST with reinforcement with a synthetic mesh.

The added risk of flap issues is not a newcomer to the experiences from other surgeons with long flaps and a reported incidence in 5 (15.1%) patients from our study in the early group. Kingsnorth et al.²⁵ has recorded results from the use of fibrin sealant to avoid complications associated with large flaps, where as some have recommended inverting the skin graft overlying the bowel instead of excising it²⁶, using a posterior component separation technique²⁷, using a so-called open-book variation¹², and the use of a subfascial absorbable mesh buttress combined with a rectus turn-over flap¹³. The 5 patients in our study showed gangrenous changes that was a matter of alarm but whether the ventral defect and its parieties condition during the act of delay is a question needing further research, as this finding was significant. (p=0.021)

In the study by Kingsnorth et al.²⁵ the frequency of seroma was 9.5 % where as in our study from both groups one in every 4 patients had clinical evidence of seroma, which was alarming but more alarming was the frequency of infection at the surgical site that was 1.7% in that study. This suggests the higher infection rate in our study but fails to demonstrate the difference between groups adding that this was also in part the difference between the study designs of the two studies and moreover the environment that we provide our patients.

Like any study on hernia the complication that the patient most dreadfully fails to accept is that of recurrence. The rates of recurrence as discussed from literature is not much in difference although some authors may document immaculate data that shows very little recurrence. With those figures the recurrence rate in our study in both groups was similar, but what was more important was that the timing of the surgery had no impact on the recurrence rate.

In a study by Kokotovic et al.⁵ the author concluded that delaying the repair beyond 12 month makes a near tension free repair impossible leading to an increased recurrence rate. Earlier studies that focused on the timing of surgery in such cases were purely retrospective^{4,7,8} lacking the evidence to suggest an ideal time to operate on such cases leaves a need to extend research to a longer duration with more number of cases. Even in our study there was limitations of number of cases and there still remains need for multicenter trials that enroll larger series of patients as well as longer follow-up to reach a conclusion of an ideal timing and procedure for such complicated hernias.

CONCLUSION

Component Separation technique is a feasible staged approach to management of a ventral wall defect (incisional hernia) with reinforcement of the wall with polypropylene mesh. With the significant chances of a flap necrosis, there is need to focus on measures to reduce the chance for an early repair of incisional hernia in a patient with prolonged hospitalization and resumption to work.

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